



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: April 30, 2003

EPA Reg No./ File Symbol  
40810-18

Page 1 of 8

Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation  
540 White Plains Road  
PO Box 2005  
Tarrytown, NY 10591-9005

Product: Irgaguard® B5000 Manufacturing Use

Ingredient: silver (PC 72501) and zinc (PC 129015)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>PRODUCT SPECIFIC DATA</b>					
OPPTS 830.1550	Product Identity and Composition	45618301	Ciba Specialty Chemicals	Own	
OPPTS 830.1600	Description of Starting Materials	45618301	Ciba Specialty Chemicals	Own	
OPPTS 830.1650	Description of the Formulation Process	45618301	Ciba Specialty Chemicals	Own	
OPPTS 830.1670	Discussion of the Formation of Impurities	45618301	Ciba Specialty Chemicals	Own	
OPPTS 830.1750	Certified Limits	45618301	Ciba Specialty Chemicals	Own	
OPPTS 830.1800	Enforcement analytical method	45618301	Ciba Specialty Chemicals	Own	
OPPTS 830.6303	Physical state	45618302	Ciba Specialty Chemicals	Own	
OPPTS 830.7000	pH	45618302	Ciba Specialty Chemicals	Own	
OPPTS 830.6314	Oxidation/reduction: chemical incompatibility	Waived	Ciba Specialty Chemicals	Own	
OPPTS 830.6320	Corrosion characteristics	Waived	Ciba Specialty Chemicals	Own	
OPPTS 830.6302	Color	45618302	Ciba Specialty Chemicals	Own	
OPPTS 830.6304	Odor	45618302	Ciba Specialty Chemicals	Own	
OPPTS 830.6315	Flammability	Waived	Ciba Specialty Chemicals	Own	
OPPTS 830.6316	Explosibility	45618303	Ciba Specialty Chemicals	Own	
OPPTS 830.6319	Miscibility	Waived	Ciba Specialty Chemicals	Own	
OPPTS 830.7100	Viscosity	Waived	Ciba Specialty Chemicals	Own	
OPPTS 830.7300	Density	45618302	Ciba Specialty Chemicals	Own	
OPPTS 870.1100	Acute oral toxicity – rat	45618304	Ciba Specialty Chemicals	Own	
OPPTS 870.1200	Acute dermal toxicity – rat	45618305	Ciba Specialty Chemicals	Own	
OPPTS 870.1300	Acute inhalation toxicity	45618306	Ciba Specialty Chemicals	Own	
OPPTS 870.2400	Primary eye irritation – rabbit	45618307	Ciba Specialty Chemicals	Own	
OPPTS 870.2500	Primary dermal irritation	45618308	Ciba Specialty Chemicals	Own	

Signature

Name and Title

Naeem Mady  
Head, Regulatory Affairs

Date

4/30/2003



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## DATA MATRIX

Date: April 30, 2003	EPA Reg No./ File Symbol 40810-18	Page 2 of 8
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B5000 Manufacturing Use	
Ingredient: silver (PC 72501) and zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 870.2600	Dermal sensitization	45618309	Ciba Specialty Chemicals	Own	
Special study	Migration per FDA protocols	45803302	Ciba Specialty Chemicals	Own	
<b>PRODUCT SPECIFIC DATA FOR SOURCE PRODUCT</b>					
OPPTS 830.1550	Product Identity and Composition	45618601	Ciba Specialty Chemicals	Own	40810-19
OPPTS 830.1600	Description of Starting Materials	45618601	Ciba Specialty Chemicals	Own	40810-19
OPPTS 830.1620	Description of the production Process	45618601	Ciba Specialty Chemicals	Own	40810-19
OPPTS 830.1670	Discussion of the Formation of Impurities	45618601	Ciba Specialty Chemicals	Own	40810-19
OPPTS 830.1700	Preliminary analysis	45618601	Ciba Specialty Chemicals	Own	40810-19
OPPTS 830.1750	Certified Limits	45618601	Ciba Specialty Chemicals	Own	40810-19
OPPTS 830.1800	Enforcement analytical method	45618601	Ciba Specialty Chemicals	Own	40810-19
OPPTS 830.6303	Physical state	45618602	Ciba Specialty Chemicals	Own	40810-19
OPPTS 830.7000	pH	45618602	Ciba Specialty Chemicals	Own	40810-19
OPPTS 830.6314	Oxidation/reduction: chemical incompatibility	Waived	Ciba Specialty Chemicals	Own	40810-19
OPPTS 830.6320	Corrosion characteristics	Waived	Ciba Specialty Chemicals	Own	40810-19
OPPTS 830.6302	Color	45618602	Ciba Specialty Chemicals	Own	40810-19
OPPTS 830.6304	Odor	45618602	Ciba Specialty Chemicals	Own	40810-19
OPPTS 830.6315	Flammability	Waived	Ciba Specialty Chemicals	Own	40810-19
OPPTS 830.6316	Explosibility	45618603	Ciba Specialty Chemicals	Own	40810-19
OPPTS 830.6319	Miscibility	Waived	Ciba Specialty Chemicals	Own	40810-19
OPPTS 830.7100	Viscosity	Waived	Ciba Specialty Chemicals	Own	40810-19
OPPTS 830.7300	Density	45618602	Ciba Specialty Chemicals	Own	40810-19
870.1100	Acute oral toxicity – rat	45618604	Ciba Specialty Chemicals	Own	40810-19

Signature <i>Naeem Mady</i>	Name and Title Naeem Mady Head, Regulatory Affairs	Date 4/30/2003
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## DATA MATRIX

Date: April 30, 2003	EPA Reg No./ File Symbol 40810-18	Page 3 of 8
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B5000 Manufacturing Use	
Ingredient: silver (PC 72501) and zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1200	Acute dermal toxicity – rat	45618605	Ciba Specialty Chemicals	Own	40810-19
870.1300	Acute inhalation toxicity	45618606	Ciba Specialty Chemicals	Own	40810-19
870.2400	Primary eye irritation – rabbit	45618607	Ciba Specialty Chemicals	Own	40810-19
870.2500	Primary dermal irritation	45618608	Ciba Specialty Chemicals	Own	40810-19
870.2600	Dermal sensitization	45618609	Ciba Specialty Chemicals	Own	40810-19
<b>GENERIC DATA - SILVER</b>					
830.6302	Color	NA	Per page 5 of Silver RED, TGAI requirements are satisfied by MP data		Agency phone call 4/22/03
830.6303	Physical state	NA	Per page 5 of Silver RED, TGAI requirements are satisfied by MP data		Agency phone call 4/22/03
830.6304	Odor	NA	Per page 5 of Silver RED, TGAI requirements are satisfied by MP data		Agency phone call 4/22/03
830.6313	Stability	NA	Per page 5 of Silver RED, TGAI requirements are satisfied by MP data		Agency phone call 4/22/03
830.7000	PH	NA	Per page 5 of Silver RED, TGAI requirements are satisfied by MP data		Agency phone call 4/22/03
830.7200	Melting point	NA	Per page 5 of Silver RED, TGAI requirements are satisfied by MP data		Agency phone call 4/22/03
830.7220	Boiling point	NA	Per page 5 of Silver RED, TGAI requirements are satisfied by MP data		Agency phone call 4/22/03
830.7300	Density/relative density/bulk density	NA	Per page 5 of Silver RED, TGAI requirements are satisfied by MP data		Agency phone call 4/22/03

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Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B5000 Manufacturing Use	
Ingredient: silver (PC 72501) and zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7370	Dissociation constant	NA	Per page 5 of Silver RED, TGAI requirements are satisfied by MP data		Agency phone call 4/22/03
830.7840-7860	Solubility	NA	Per page 5 of Silver RED, TGAI requirements are satisfied by MP data		Agency phone call 4/22/03
830.7950	Vapor pressure	NA	Per page 5 of Silver RED, TGAI requirements are satisfied by MP data		Agency phone call 4/22/03
870.1100	Acute oral toxicity – rat	42032702, 42664501	Kanebo	Per	Footnote 10
870.1200	Acute dermal toxicity – rat	42032702, 42664501	Kanebo	Per	Footnote 10
870.1300	Acute inhalation toxicity	42032702, 42664501	Kanebo	Per	Footnote 10
870.2400	Primary eye irritation – rabbit	42032702, 42664501	Kanebo	Per	Footnote 10
870.2500	Primary dermal irritation	42032702, 42664501	Kanebo	Per	Footnote 10
870.2600	Dermal sensitization	42032702, 42664501	Kanebo	Per	Footnote 10
870.3250	90 day oral toxicity – rodent	RED Ref		Pub	Footnote 1
870.3150	90 day oral toxicity, non-rodent				
870.3700	Developmental toxicity – rodent	RED Ref		Pub	Footnote 2
870.3800	Two-generation reproduction - rodent				
870.5265	In vitro mutagenicity	RED Ref		Pub	Footnote 3
870.5300	Mutagenicity – mammalian cells in culture	RED Ref		Pub	Footnote 3

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Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B5000 Manufacturing Use	
Ingredient: silver (PC 72501) and zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5380	In vivo cytogenetics	RED Ref		Pub	Footnote 3
850.1010	Daphnia acute toxicity	42650501	Mason Chemical	Pay	
850.1075	Acute toxicity – fish	42650501	Mason Chemical	pay	
850.2100	Avian Acute toxicity	43312901	Mason Chemical	Pay	
835.2120	Hydrolysis	RED Ref		Pub	Footnote 4
<b>GENERIC DATA – ZINC</b> Per EPA letter of 4/17/03, reference zinc oxide					
830.6302	Color	41777903	Monsanto	Pay	Footnote 11
830.6303	Physical state	41777903	Monsanto	Pay	Footnote 11
830.6304	Odor	41777903	Monsanto	Pay	Footnote 11
830.6313	Stability	41777903	Monsanto	Pay	Footnote 11
830.7000	pH	41777903	Monsanto	Pay	Footnote 11
830.7200	Melting point	41777903	Monsanto	Pay	Footnote 11
830.7220	Boiling point	41777903	Monsanto	Pay	Footnote 11
830.7300	Density/relative density/bulk density	41777903	Monsanto	Pay	Footnote 11
830.7370	Dissociation constant	41777903	Monsanto	Pay	Footnote 11
830.7840-7860	Solubility	41777903	Monsanto	Pay	Footnote 11
830.7950	Vapor pressure	41777903	Monsanto	Pay	Footnote 11
870.1100	Acute oral toxicity – rat	147624	Monsanto	Old	Footnote 11
870.1200	Acute dermal toxicity – rat	147625	Monsanto	Old	Footnote 11
870.1300	Acute inhalation toxicity	43258601	Monsanto	Pay	Footnote 11
870.2400	Primary eye irritation – rabbit	147627	Monsanto	Old	Footnote 11
Signature <i>Naeem Mady</i>			Name and Title Naeem Mady Head, Regulatory Affairs		Date 4/30/2003



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Ingredient: silver (PC 72501) and zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2500	Primary dermal irritation	147626	Monsanto	Old	Footnote 11
870.2600	Dermal sensitization	43258602	Monsanto	pay	Footnote 11
870.3250	90 day dermal toxicity - rodent	RED Ref		Pub	Footnote 5, 9
870.3150	90 day oral toxicity, non-rodent				
870.3700	Developmental toxicity - rodent	RED Ref		Pub	Footnote 7, 9
870.3800	Two-generation reproduction - rodent				
870.5265	In vitro mutagenicity	RED Ref		Pub	Footnote 7, 9
870.5300	Mutagenicity - mammalian cells in culture	RED Ref		Pub	Footnote 7, 9
870.5380	In vivo cytogenetics	RED Ref		pub	Footnote 7, 9
850.1010	Daphnia acute toxicity	155227	Monsanto	old	
850.1075	Acute toxicity - fish	155224 155228	Monsanto	old	
850.2100	Avian Acute toxicity	155226	Monsanto	old	
835.2120	Hydrolysis	RED Ref		pub	Footnote 8, 9

Footnote 1: Published literature references cited in Silver RED (US EPA 1993):

- Wagner, P.A., Hoekstro, W. and Ganther, H.E. 1975. Alleviation of silver toxicity by selenite in the rat in relation to tissue glutathione peroxidase. Proc. Soc. Exp. Biol. Med. 148:1106-1420
- Van Vleet, J.F. 1976. Induction of lesions of Selenium-vitamin E deficiency in pigs fed silver. Am. J. Vet. Res. 37:1425-1420
- Day, W.A., Hunt, J.S. and McGiven, A.R. 1976. Silver deposition in mouse glomeruli. Pathology 8:201-204
- Walker, F. 1971. Experimental Argyria: A model for basement membrane studies. Brit. J. Exp. Path. 52:589-593
- Olcott, C.T. 1947. Experimental argyrosis. III. Pigmentation of the eyes of rats following ingestion of silver during long periods of time. Am. J. Path. 23:783-789.
- Olcott, C.T. 1948. Experimental argyrosis. IV. Morphological changes in the experimental animal. Am. J. Path. 24: 813-833.
- Olcott, C.T. 1950. Experimental argyrosis. V. Hypertrophy of the left ventricle of the heart in rats ingesting silver salts. Arch. Path. 49: 138-149.
- U.S. DHHS. PHS. Agency for Toxic Substances and Diseases Registry, Dec. 1990. Toxicology Profile for Silver. Publ. No. TP-90-24

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Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B5000 Manufacturing Use	
Ingredient: silver (PC 72501) and zinc (PC 129015)		

- Goyer, R.A. 1991. Toxic effects of metals. Casserett and Doull's Toxicology. Eds. M. Amdur, J. Doull, and C. Klaassen. Pergamon Press. 623-280.
- Gaul, L.E., and Staud, A.H. 1935. Clinical Spectroscopy. Seventy cases of generalized argyrosis following organic and colloidal silver medication, including a biospectrometric analysis of ten cases. J. Am. Med. Assoc. 104:1387-1390

Footnote 2: Published literature references cited in Silver RED (US EPA 1993):

- Rungby, J, Slomianka, L., Dansker, G., Anderson, A.H., and West, M.J. 1987. A quantitative evaluation of the neurotoxic effect of silver on the volumes of the components of the developing rat hippocampus. Toxicol. 43:261-268
- U.S. DHHS. PHS. Agency for Toxic Substances and Diseases Registry, Dec. 1990. Toxicology Profile for Silver. Publ. No. TP-90-24

Footnote 3: Published literature references cited in Silver RED (US EPA 1993):

- Demerec, M., Bertani, G., and Fling, J. 1951. A survey of chemicals for mutagenic action on E. Coli. Am. Nat. 85:119-136.
- Nishioka, H. 1975. Mutagenic activity of metal compounds in bacteria. Mutat. Res 31: 185-189.
- U.S. DHHS. PHS. Agency for Toxic Substances and Diseases Registry, Dec. 1990. Toxicology Profile for Silver. Publ. No. TP-90-24
- Rossman, T.G., and Molina, M. 1986. The genetic toxicology of metal compounds: II. Enhancement of ultraviolet light-induced mutagenesis in Escherichia coli WP2. Environ. Mutagen 8:263-271.

Footnote 4: Published literature references cited in Silver RED (US EPA 1993):

- U.S. DHHS. PHS. Agency for Toxic Substances and Diseases Registry, Dec. 1990. Toxicology Profile for Silver. Publ. No. TP-90-24
- Buffle, J. Complexation Reactions in aquatic chemistry: An analytical approach. 1990. Ellis Horwood, NY
- Cotton, F.A., and Wilkenson G. Advanced Inorganic Chemistry. Fifth Edition 1988. John Wiley and Sons, NY
- Greenwood, N.N. and Earnshaw, A. Chemistry of the Elements. 1984. Pergamon Press Ltd., Oxford, UK
- Irgolic, K.J., and Martell, A.E. Environmental Inorganic Chemistry. 1985. VCH Publishers, Inc.
- Morel, F.M.M. Principles of aquatic chemistry. 1983. John Wiley and Sons, NY.
- Muller, A. and Krebs, B. Studies in inorganic chemistry. Vol. 5: sulfur: its significance to chemistry. For the Geo- Bio- and Cosmosphere and Technology. 1984. Elsevier Publishers, Amsterdam.
- Murr, L.E. Intervacial phenomena in metals and alloys. 1975. Addison Wesley Publishing Company, Reading MA
- Pourbaix, M. Atlas of electrochemical equilibria in aqueous solutions, 1974. Translated by J.A. Franklin, National Association of Corrosion Engineers, Houston, TX
- Reese, R.J. "Silver", Minerals Facts and Problems. U.S. Department of the Interior, Bureau of Mines; Bulletin 675, 1985 Edition, U.S. Printing Office, Washington DC

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Ingredient: silver (PC 72501) and zinc (PC 129015)		

- Shumilova, N.A. and Zhutaeva, G.V. "Silver" in Encyclopedia of Electrochemistry of the Elements. A.J. Bard, Ed. Vol III. 1978. Marcel Dekker, Inc. NY.
- "Silver Compounds" in Kirk-Othmer Encyclopedia of Chemical Technology, 3<sup>rd</sup> Ed. 1983. John Wiley and Sons, NY
- Stumm, W. Chemistry of the solid-water interface: processes at the mineral-water and particle-water interface in natural systems, 1992. John Wiley and Sons, NY
- Thompson, N.R. "Silver" Comprehensive Inorganic Chemistry. J.C. Bailar, Ed., 1973, Pergamon Press, UK
- Zhutaeva, G.V., and Shumilova, N.A. "Silver", in Standard Potentials in Aqueous Solution, A.J. Bard, R. Parsons, and J. Jordan Ed. Prepared under the auspices of IUPAC, Physical and Analytical Chemistry Divisions, Commissions on Electrochemistry and Electroanalytical Chemistry. 1985. Marcel Dekker, NY.

Footnote 5: Published literature references cited in Zinc Salts RED (US EPA 1992):

- FASEB, 1973. Evaluation of the Health Aspects of certain zinc salts as food ingredients. SCOGS-21

Footnote 6: Published literature references cited in Zinc Salts RED (US EPA 1992):

- NIOSH. 1987. Registry of Toxic Effects of Chemical Substances. Washington, DC
- FASEB, 1973. Evaluation of the Health Aspects of certain zinc salts as food ingredients. SCOGS-21

Footnote 7: Published literature references cited in Zinc Salts RED (US EPA 1992):

- Sax, N. and Lweis, R. 1989. Dangerous Properties of Industrial Materials. 7<sup>th</sup> Ed. Van Nostrand Reinhold, NY
- NIOSH. 1987. Registry of Toxic Effects of Chemical Substances. Washington, DC

Footnote 8: Published literature references cited in Zinc Salts RED (US EPA 1992):

- RED pages 6, 11
- NIOSH. 1987. Registry of Toxic Effects of Chemical Substances. Washington, DC

Footnote 9: Published literature references:

- U.S. DHHS. PHS. Agency for Toxic Substances and Diseases Registry, Dec. 1994. Toxicology Profile for Zinc.
- WHO. 2001. Environmental Health Criteria – Zinc. EHC 221.
- FNB. 2002. Dietary reference intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc. National Academies of Science, Food and Nutrition Board. National Academies Press.

Footnote 10: Per Agency agreement on 4/22/03, TGAI requirements are fulfilled by Bactekiller A, 3.5% silver in zeolite, EPA Reg. No. 59824-3.

Footnote 11: Cited data are from EPA Reg. No. 524-354 (registration transferred to 71645-3), a 99.4% zinc oxide product and are cited in the RED or fulfilled RED DCI requirements.

Signature <i>Naeem Mady</i>	Name and Title Naeem Mady Head, Regulatory Affairs	Date 4/30/2003
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Ingredient: silver (PC 72501) and zinc (PC 129015)		

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			Ciba Specialty Chemicals	Own	

Signature <i>Naeem H. Mady</i>	Name and Title Naeem Mady Head, Regulatory Affairs	Date 4/30/2003
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## DATA MATRIX

Date: April 30, 2003

EPA Reg No./ File Symbol  
40810-18

Page 2 of 8

Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation  
540 White Plains Road  
PO Box 2005  
Tarrytown, NY 10591-9005

Product: Irgaguard® B5000 Manufacturing Use

Ingredient: silver (PC 72501) and zinc (PC 129015)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	
			Ciba Specialty Chemicals	Own	40810-19
			Ciba Specialty Chemicals	Own	40810-19
			Ciba Specialty Chemicals	Own	40810-19
			Ciba Specialty Chemicals	Own	40810-19
			Ciba Specialty Chemicals	Own	40810-19
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			Ciba Specialty Chemicals	Own	40810-19
			Ciba Specialty Chemicals	Own	40810-19
			Ciba Specialty Chemicals	Own	40810-19
			Ciba Specialty Chemicals	Own	40810-19

Signature

*Naeem Mady*

Name and Title

Naeem Mady  
Head, Regulatory Affairs.

Date

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## DATA MATRIX

Date: April 30, 2003	EPA Reg No./ File Symbol 40810-18	Page 3 of 8
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B5000 Manufacturing Use	
Ingredient: silver (PC 72501) and zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Ciba Specialty Chemicals	Own	40810-19
			Ciba Specialty Chemicals	Own	40810-19
			Ciba Specialty Chemicals	Own	40810-19
			Ciba Specialty Chemicals	Own	40810-19
			Ciba Specialty Chemicals	Own	40810-19
			Per page 5 of Silver RED, TGAI requirements are satisfied by MP data		Agency phone call 4/22/03
			Per page 5 of Silver RED, TGAI requirements are satisfied by MP data		Agency phone call 4/22/03
			Per page 5 of Silver RED, TGAI requirements are satisfied by MP data		Agency phone call 4/22/03
			Per page 5 of Silver RED, TGAI requirements are satisfied by MP data		Agency phone call 4/22/03
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			Per page 5 of Silver RED, TGAI requirements are satisfied by MP data		Agency phone call 4/22/03
			Per page 5 of Silver RED, TGAI requirements are satisfied by MP data		Agency phone call 4/22/03

Signature <i>Nacem Mady</i>	Name and Title Nacem Mady Head, Regulatory Affairs	Date 4/30/2003
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## DATA MATRIX

Date: April 30, 2003	EPA Reg No./ File Symbol 40810-18	Page 4 of 8
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B5000 Manufacturing Use	
Ingredient: silver (PC 72501) and zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Per page 5 of Silver RED, TGA1 requirements are satisfied by MP data		Agency phone call 4/22/03
			Per page 5 of Silver RED, TGA1 requirements are satisfied by MP data		Agency phone call 4/22/03
			Per page 5 of Silver RED, TGA1 requirements are satisfied by MP data		Agency phone call 4/22/03
			Kanebo	Per	Footnote 10
			Kanebo	Per	Footnote 10
			Kanebo	Per	Footnote 10
			Kanebo	Per	Footnote 10
			Kanebo	Per	Footnote 10
			Kanebo	Per	Footnote 10
				Pub	Footnote 1
				Pub	Footnote 2
				Pub	Footnote 3
				Pub	Footnote 3

Signature

Name and Title

Naeem Mady  
Head, Regulatory Affairs

Date

4/30/2003



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Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B5000 Manufacturing Use	
Ingredient: silver (PC 72501) and zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				Pub	Footnote 3
			Mason Chemical	Pay	
			Mason Chemical	pay	
			Mason Chemical	Pay	
				Pub	Footnote 4
			Monsanto	Pay	Footnote 11
			Monsanto	Pay	Footnote 11
			Monsanto	Pay	Footnote 11
			Monsanto	Pay	Footnote 11
			Monsanto	Pay	Footnote 11
			Monsanto	Pay	Footnote 11
			Monsanto	Pay	Footnote 11
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			Monsanto	Pay	Footnote 11
			Monsanto	Pay	Footnote 11
			Monsanto	Pay	Footnote 11
			Monsanto	Old	Footnote 11
			Monsanto	Old	Footnote 11
			Monsanto	Pay	Footnote 11
Monsanto	Old	Footnote 11			
Signature <i>Naeem Mady</i>			Name and Title Naeem Mady Head, Regulatory Affairs		Date 4/30/2003



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## DATA MATRIX

Date: April 30, 2003	EPA Reg No./ File Symbol 40810-18	Page 6 of 8
Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B5000 Manufacturing Use	
Ingredient: silver (PC 72501) and zinc (PC 129015)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto	Old	Footnote 11
			Monsanto	pay	Footnote 11
				Pub	Footnote 5, 9
				Pub	Footnote 7, 9
				Pub	Footnote 7, 9
				Pub	Footnote 7, 9
				pub	Footnote 7, 9
			Monsanto	old	
			Monsanto	old	
			Monsanto	old	
				pub	Footnote 8, 9

Footnote 1: Published literature references cited in Silver RED (US EPA 1993):

- Wagner, P.A., Hoekstro, W. and Ganther, H.E. 1975. Alleviation of silver toxicity by selenite in the rat in relation to tissue glutathione peroxidase. Proc. Soc. Exp. Biol. Med. 148:1106-1420
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- Olcott, C.T. 1950. Experimental argyrosis. V. Hypertrophy of the left ventricle of the heart in rats ingesting silver salts. Arch. Path. 49: 138-149.
- U.S. DHHS. PHS. Agency for Toxic Substances and Diseases Registry, Dec. 1990. Toxicology Profile for Silver. Publ. No. TP-90-24

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Applicant's/Registrant's Name and Address: Ciba Specialty Chemicals Corporation 540 White Plains Road PO Box 2005 Tarrytown, NY 10591-9005	Product: Irgaguard® B5000 Manufacturing Use	
Ingredient: silver (PC 72501) and zinc (PC 129015)		

- Goyer, R.A. 1991. Toxic effects of metals. Casserett and Doull's Toxicology. Eds. M. Amdur, J. Doull, and C. Klaassen. Pergamon Press. 623-280.
- Gaul, L.E., and Staud, A.H. 1935. Clinical Spectroscopy. Seventy cases of generalized argyrosis following organic and colloidal silver medication, including a biospectrometric analysis of ten cases. J. Am. Med. Assoc. 104:1387-1390

Footnote 2: Published literature references cited in Silver RED (US EPA 1993):

- Rungby, J, Slomianka, L., Dansker, G., Anderson, A.H., and West, M.J. 1987. A quantitative evaluation of the neurotoxic effect of silver on the volumes of the components of the developing rat hippocampus. Toxicol. 43:261-268
- U.S. DHHS. PHS. Agency for Toxic Substances and Diseases Registry, Dec. 1990. Toxicology Profile for Silver. Publ. No. TP-90-24

Footnote 3: Published literature references cited in Silver RED (US EPA 1993):

- Demerec, M., Bertani, G., and Fling, J. 1951. A survey of chemicals for mutagenic action on E. Coli. Am. Nat. 85:119-136.
- Nishioka, H. 1975. Mutagenic activity of metal compounds in bacteria. Mutat. Res 31: 185-189.
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Footnote 4: Published literature references cited in Silver RED (US EPA 1993):

- U.S. DHHS. PHS. Agency for Toxic Substances and Diseases Registry, Dec. 1990. Toxicology Profile for Silver. Publ. No. TP-90-24
- Buffle, J. Complexation Reactions in aquatic chemistry: An analytical approach. 1990. Ellis Horwood, NY
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Date: April 30, 2003	EPA Reg No./ File Symbol 40810-18	Page 8 of 8
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Ingredient: silver (PC 72501) and zinc (PC 129015)		

- Shumilova, N.A. and Zhutaeva, G.V. "Silver" in Encyclopedia of Electrochemistry of the Elements. A.J. Bard, Ed. Vol III. 1978. Marcel Dekker, Inc. NY.
- "Silver Compounds" in Kirk-Othmer Encyclopedia of Chemical Technology, 3<sup>rd</sup> Ed. 1983. John Wiley and Sons, NY
- Stumm, W. Chemistry of the solid-water interface: processes at the mineral-water and particle-water interface in natural systems, 1992. John Wiley and Sons, NY
- Thompson, N.R. "Silver" Comprehensive Inorganic Chemistry. J.C. Bailar, Ed., 1973, Pergamon Press, UK
- Zhutaeva, G.V., and Shumilova, N.A. "Silver", in Standard Potentials in Aqueous Solution, A.J. Bard, R. Parsons, and J. Jordan Ed. Prepared under the auspices of IUPAC, Physical and Analytical Chemistry Divisions, Commissions on Electrochemistry and Electroanalytical Chemistry. 1985. Marcel Dekker, NY.

Footnote 5: Published literature references cited in Zinc Salts RED (US EPA 1992):

- FASEB, 1973. Evaluation of the Health Aspects of certain zinc salts as food ingredients. SCOGS-21

Footnote 6: Published literature references cited in Zinc Salts RED (US EPA 1992):

- NIOSH. 1987. Registry of Toxic Effects of Chemical Substances. Washington, DC
- FASEB, 1973. Evaluation of the Health Aspects of certain zinc salts as food ingredients. SCOGS-21

Footnote 7: Published literature references cited in Zinc Salts RED (US EPA 1992):

- Sax, N. and Lweis, R. 1989. Dangerous Properties of Industrial Materials. 7<sup>th</sup> Ed. Van Nostrand Reinhold, NY
- NIOSH. 1987. Registry of Toxic Effects of Chemical Substances. Washington, DC

Footnote 8: Published literature references cited in Zinc Salts RED (US EPA 1992):

- RED pages 6, 11
- NIOSH. 1987. Registry of Toxic Effects of Chemical Substances. Washington, DC

Footnote 9: Published literature references:

- U.S. DHHS. PHS. Agency for Toxic Substances and Diseases Registry, Dec. 1994. Toxicology Profile for Zinc.
- WHO. 2001. Environmental Health Criteria – Zinc. EHC 221.
- FNB. 2002. Dietary reference intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc. National Academies of Science, Food and Nutrition Board. National Academies Press.

Footnote 10: Per Agency agreement on 4/22/03, TGAI requirements are fulfilled by Bactekiller A, 3.5% silver in zeolite, EPA Reg. No. 59824-3.

Footnote 11: Cited data are from EPA Reg. No. 524-354 (registration transferred to 71645-3), a 99.4% zinc oxide product and are cited in the RED or fulfilled RED DCI requirements.

Signature <i>Nacem Mady</i>	Name and Title Nacem Mady Head, Regulatory Affairs	Date 4/30/2003
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